

## **REMARKS**

### **Status of the Claims**

By virtue of the Listing of Claims presented herein, claims 61, 62, 64-67 and 69-92, and 95-102 are pending.

Claims 1-60, 63, 68, 93, 94, and 103-107 are canceled without prejudice. Applicant reserves the right to prosecute the subject-matter of these claims in a continuing application.

Claims 61 and 62 have been amended to replace the term “a” with the term “the” in order to enhance clarity. Basis for the amendments is found through out the specification; for example, at Figures 1, 3, 4, 5, and 6 as well as the description of such Figures (e.g., at page 11, line 12, through page 12, line 24), and in the Sequence Listing at SEQ ID:NOS 2, 4, 5, and 6, which collectively disclose the amino acid sequences recited in the claims. Claim 62 has also been amended to include the term “polypeptide”, as indicated, in order to correct a minor typographical error.

Claims 69 through 74 have been amended to remove dependency from deleted claims.

Claim 77 has been amended to recite that the recited host cell comprises an isolated host cell or a cultured host cell. Basis for the amendment is found, for example, at page 42, lines 3 through 10, as well as throughout the Examples section, which describes, for example, isolation and culturing of exemplary host cells harboring exemplary OB- encoding vectors.

No new matter is introduced by way of the amendments to the claims.

All claim cancellations and claim amendments made in the subject application are made, and have been made, with the express proviso that all canceled, omitted, amended, or deleted subject matter is so-canceled, -omitted, -amended, or -deleted without prejudice or disclaimer to the right to pursue such subject matter in one or more continuation, continuation-in-part, or divisional applications.

### **Claim Rejections**

#### **Rejection under 35 U.S.C. § 112, first paragraph: written description**

##### **Claim 63**

Claim 63, and claims 69-88 and 93 – 107 dependant therefrom, are rejected under 35

U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For the reasons set forth in Applicant's response(s) filed throughout the history of the subject application, Applicant continues to vehemently disagree with the Examiner's assertions concerning an alleged lack of representative number of species encompassed by the genus recited in Claim 63, for the reasons made of record by Applicant's previous responses, at least. Nonetheless, in order to advance the subject case, Applicant has canceled Claims 63, 93, 94, and 103 through 107 without prejudice or disclaimer, thereby rendering that portion of the rejection directed to such claims moot. The amendments to claims 69 through 74 render that portion of the rejection directed to claims 69 through 88 and 95-102 moot.

#### Claims 61-62

Claims 61-62 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner continues to assert that the phrase, "wherein said OB polypeptide comprises an amino acid sequence set out in" allegedly "encompasses any and all sequences which could be made from the reference of SEQ ID NO:2, 4, 5, or 6 – this includes fragments and non-contiguous sequences of the reference."

Applicant continues to vigorously disagree with the Examiner's assertions, for the reasons of record by way of Applicant's previous responses. Nonetheless, in order to advance the subject case, Applicant has amended Claims 61 and 62 to recite that the recited OB polypeptide comprises "the" amino acid sequence selected from among the sequences recited in subparts (a), (b), (c), and (d). The Examiner has stated that the "rejection could be avoided" by way of such amendment (see, e.g., Office Action mailed June 6, 2008, page 11). Accordingly, the rejection is rendered moot.

#### Claims 103-107

Claims 103-107 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to

comply with the written description requirement insofar as the claims allegedly contain new matter. Applicant vigorously disagrees with the Examiner's assertions. Nonetheless, in order to advance the subject case, Applicant has canceled Claims 103-107, thereby rendering the rejection moot.

Rejection under 35 U.S.C. § 112, first paragraph: enablement

Claim 77 stands rejected because the specification, while enabling an isolated or cultured cell comprising an expression vector, allegedly does not reasonably enable host cells in the context of a multicellular, transgenic organism, or as host cells intended for gene therapy. Further, the Examiner continues to assert that the instant specification does not enable the skilled artisan to make and use the invention commensurate with the scope of the claims. The Examiner contends at length that there are no "methods or working examples" demonstrating transplantation of cells expressing an OB polypeptide for a therapeutic purpose or where gene therapy is performed on a human, and insists that the alleged unpredictability associated with gene expression in transgenic animals would necessitate undue experimentation in order to employ such host cells for generating a transgenic animal or providing for expressing an OB nucleic acid in a cell of an organism for gene therapy. The Examiner continues to assert that "the unpredictability in the art is *very high* for making transgenic animals"(emphasis in original) for the reasons set forth in the previous Action.

Applicants continue to vigorously disagree with these assertions, for reasons of record by way of Applicant's previous responses, at least. Nonetheless, in order to advance the subject case and not in acquiescence to the rejection, Applicant has amended the claim to recite that the recited host cell comprises an isolated host cell or a cultured host cell. The Examiner has stated the claim is "enabling for an isolated or cultured cell comprising an expression vector" as recited in the instant claims (see, e.g., Office Action mailed June 6, 2008, page 12, lines 1 through 3). Applicant respectfully requests the reconsideration and withdrawal of this rejection.

Provisional rejection under the judicially created doctrine of obviousness-type double patenting

Claims 61-67 and 69-88 remain rejected, and claims 89-102 are now rejected under the

judicially created doctrine of double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 5,935,810 and claims 1-21 of U.S. Patent No. 6,309,853, and further in view of Davis et al. (U.S. Patent No. 4,179,337) and Stahl et al. (U.S. Patent No. 5,470,843).

Applicant vigorously disagrees with the Examiner's assertions. In particular, Applicant notes that the Examiner's comments concerning alleged references to the teachings of the specification of the subject application are unclear - Applicant never referred to the specification of the subject application in his arguments; Applicant's references to specifications were made with respect to passages in the specification of the patents as cited by the Examiner in support of the rejection.

Nonetheless, in order to advance the subject case, Applicant provides herewith two Terminal Disclaimers: one with respect to U.S. Patent No. 6, 309, 853, the other with respect to U.S. Patent 4,179,337. Each Terminal Disclaimer complies with the provisions of 37 C.F.R. 1.321(c) or 1.321(d). Accordingly, the provisional rejection under the judicially created doctrine of obviousness-type double patenting is rendered moot.

CONCLUSION


In conclusion, all rejections outlined in the outstanding Office Action rendered moot by way of the foregoing.

Applicants believe that all issues raised in the Office Action have been properly addressed in this response and in the amendments to the claims as shown in the attached Listing of Claims. Accordingly, reconsideration and allowance of the amended claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Deposit Account 19-4293 referencing Docket No. 16454.0004 C1. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Deposit Account 19-4293.

Respectfully submitted,

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